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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,458	05/09/2001	Itzhak Avital	81476-255373	5112

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EXAMINER
TON, THAIAN N

ART UNIT	PAPER NUMBER
1632	14

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,458	AVITAL ET AL.	
	Examiner	Art Unit	
	Thai-An N. Ton	1632	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-5,8-36* is/are allowed.

6)☒ Claim(s) *37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/6/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' Amendment, filed 6/16/03, Paper No. 13, has been entered. Claims 6 and 7 have been cancelled. Claims 10-12, 27-29 and 37 have been amended.

Claims 1-5 and 8-42 are pending and under current examination.

Any rejection made of record in the prior Office action, mailed 1/15/03, Paper No. 9, and not made of record in the instant Office action, has been withdrawn in view of Applicants' arguments and/or amendments to the claims.

Drawings

Applicants' drawings, filed 6/16/03, Paper No. 11, are accepted by the Examiner.

Information Disclosure Statement

The Information Disclosure Statement, filed 6/16/03, Paper No. 10, has been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of claims 1-36 under 35 U.S.C. 112, first paragraph, is *withdrawn.* The prior rejection was with respect to the enablement of the claimed invention with regard to the selection of stem cells from a sample of cells, because cells other than stem cells [*e.g.*, spermatozoa], may be included in the cells isolated by the methods of the invention. The prior rejection is withdrawn because the Examiner notes that the active step of the instant invention is the selection of stem cells, and that stem cell markers were well known in the art at the time the claimed invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The prior rejection of claims 1-20, 27 and 29 under 35 U.S.C. 112, second paragraph is *withdrawn.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The prior rejection of claims 37-42 under 35 U.S.C. 102(b) as being anticipated by Tsukamoto *et al.* [US Pat. No. 5,643,74, published July 1, 1997, cited on Applicants' Information Disclosure Citation filed April 8, 2002, Paper No. 4] is *maintained* for reasons of record.

The claims are directed to isolated stem cells that do not express β_2m, express Thy-1, is derived from the bone marrow or liver of a mammal, is a pluripotent or embryonic stem cell. Applicants have amended to the claims to recite that the isolated stem cell does not express β_2m, wherein the stem cell is isolated by obtaining a sample of cells from a mammal, sorting, from the sample, cells that express β_2m from cells that do not express β_2m and selecting the isolated stem cell from the sample of cells that do not express β_2m. See claim 37.

Applicants argue that Tsukamoto describes a method for identifying the presence of stem cells by examining the expression of particular cell surface markers. Applicants argue that Tsukamoto does not teach or disclose the process as claimed, wherein the stem cell is isolated by obtaining a sample of cells from a mammal, sorting, from the sample, cells that express β_2m from cells that do not express β_2m and selecting the isolated stem cell from the sample of cells that do not express β_2m, and that nowhere does Tsukamoto suggest the sorting of a sample of cells based on β_2m expression. See p. 9 of Applicants' Response.

Applicants' arguments have been considered, but are not found to be persuasive. As amended, claim 37 is a product-by-process claim. Where, as here,

the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Further, see MPEP §2113, "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

It is reiterated that the properties of the claimed stem cells are inherent properties of the stem cells. It is noted that, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Tsukamoto teach the identification and isolation of human hematopoietic stem cells. In particular, they teach that Thy-1 is a molecule that has been identified in rat and mouse hematopoietic stem cells [see col. 1, lines 65-67]. They further teach that the hematopoietic stem cells are pluripotent [see col. 6, lines 30-50] and that the cells were isolated from human fetal bone marrow, human fetal livers, and adult bone marrow [col. 9, lines 13-30].

Accordingly, Tsukamoto anticipate the claimed invention.

The prior rejection of claims 37, 41 and 42 under 35 U.S.C. 102(b) as being anticipated by Thomson *et al.* [**Science** 1998, 282:1145-1147, cited in the prior Office action] is *maintained* for reasons of record.

The claims are directed to an isolated stem cell that does not express β_2m, is pluripotent, and is an embryonic stem cell.

Applicants argue that Thomson described pluripotent stem cell lines that exclusively characterize primate embryonic stem cells, but do not describe the three-component process to obtain the isolated stem cell. As such, Applicants argue that Thomson does not teach, disclose, or suggest the use of the claimed process, does not suggest the sorting of sample cells based upon β_2m expression, and therefore do not describe each and every aspect of Applicants' invention. See p. 10 of Applicant's Response.

Applicants' arguments have been carefully considered, but are not found to be persuasive. The claims, as amended, are product-by-process claims. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Further, see MPEP §2113, "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

It is reiterated that the lack of expression of β_2m is an inherent quality of stem cells. It is noted that, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the

properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Thomson teach pluripotent human embryonic stem cell lines which were derived from human blastocysts [see *Abstract*].

Accordingly, Thomson anticipates the claimed invention.

Conclusion

Claims 1-5 and 8-36 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT
Thái-An N. Ton
Patent Examiner
Group 1632

Deborah Crouch

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PRIMARY EXAMINER
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